REMARKS:

Claims 1-20 are currently pending. Claims 1-3 and 6 have been amended to correct several minor grammatical errors and provide antecedent basis.

Claim 4 has been canceled.

No new matter or issues are raised by the instant amendments.

Claim Objections

Applicant has amended the claims thereby obviating the claim objections noted by the Examiner.

Claim Rejections under 35 USC §112, second paragraph

1. Claims 1 and 4, and claims 2-3, and 6 and 8-14 were rejected as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention and/or on grounds that the metes and bounds of the claims were not clear.

Applicant has amended claims 1-3 and has canceled claim 4 thereby obviating the rejection. Withdrawal is respectfully requested.

Claim Rejections under 35 USC § 112, first paragraph

1. Claims 1-3, 6 and 8-14 were rejected as failing to comply with the written description requirement. More specifically, the Examiner indicated that while the specification described homologies of at least 50, 60, 70 and 80% with SEQ ID NO:2, the specification did not describe a homology of at least 95%, and thus, the recitation thereof comprised new matter. Applicant respectfully submits that a homology of at least 95% is inherently described in homologies of at least 50, 60, 70 and 80% homologies with SEQ ID NO: 2 and would be readily recognized by an individual having ordinary skill in the art. In this regard, "[w]ith respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%- 60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement

because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement." MPEP § 2163.05 (Emphasis added).

Accordingly, Applicant respectfully submits that the claimed homology of at least 95% is inherently described in the specification and does not constitute new matter. In view thereof, the rejection should be withdrawn.

2. Claims 1-4, 6 and 8-14 were rejected for allegedly failing to comply with the written description requirement by not reasonably conveying that the Applicants were in possession of the claimed invention. Applicants have amended the claims thereby rendering the rejection moot. Notwithstanding, Applicant respectfully submits that the instant specification complies with the written description and enablement requirements.

In this regard, it must be remembered that to satisfy the written description prong of 35 USC §112 ¶1, the specification need merely describe the invention in sufficient detail so that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). No particular form of disclosure is required, but "the description must clearly allow persons of ordinary skill in the art to recognize that [the patentee] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) (citing *In re Wertheim*, 541 F.2d 257, 262 (C.C.P.A. 1976)).

The instant claims are presented in such manner that the problems of insufficient numbers of examples, as described by the Examiner, do not apply. Applicants' invention is drawn to an isolated nucleic acid sequence which encodes a fusion protein and which is composed of a combination of a nucleic acid sequence encoding a fatty acid or lipid metabolism. The MPEP states that a "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces" and as such, a single species may be enough to identify the entire genus (*see* MPEP 2163.II.A.3.a.ii.). A recent Federal Circuit case supports the statements of the MPEP. When discussing what is required for a written description the court said "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution" (*Capon v. Eshhar*, 418 F.3d 1349, 1358; (Fed. Cir. 2005)). Further, in overturning a BPAI decision, which

relied on similar rejections reasons as stated in the instant Office Action, where both parties to an interference had all Claims in their respective patents cancelled for failing to meet the written description requirement, the court stated that "[t]he Board erred in refusing to consider the state of the art of the scientific knowledge" and when citing *Lilly* and *Fiers* spoke of a rulings in view of a "wish" list provided in said inventions, and not the state of the relevant art (*Id.* at 1357). Further, the court stated, that "[i]t is not necessary that every permutation with a generally operable invention be effective in order for an inventor to obtain a generic claim" and both parties were lauded because they "present[ed] not only general teachings… but also specific examples" (*Id.* at 1359).

Applicants assert that the instant Specification fully complies with these requirements because it allows one of ordinary skill in the art to practice the invention. The claims are written in such a manner that the problems described by the Examiner in the Office Action should not apply. Even the Examiner has stated that Applicants have supplied a polynucleotide encoding a fusion protein comprising a polypeptide of SEQ ID NO: 2 and Δ-4 desaturase which provide exemplifications of the instant invention when not even a single example is required to fulfill the written description requirement. Applicant's specification provides summary information such as the function of lipids and fatty acids, and general molecular biology techniques which meet the "general teachings" prong. Further, Applicants have supplied "specific examples" of the instant invention as required of the second prong of *Capon*. The instant Specification teaches at least SEQ ID NO: 2 and Δ-4 desaturase. Thus while not required to provide even a single working example (*See, In re Gosteli* above - no specific form of the disclosure is required), Applicants have provided such specific examples as set forth above and as the Federal Circuit lauded in *Capon*.

Further still, in light of Applicants' amendment changing the percentage homology to 95%, Applicants have provided a claimed genus wherein, contrary to the Examiner's assertions, one of ordinary skill in the art would recognize that Applicants had possession of the instant invention at the time of filing. As noted above, all that is required to meet the written description prong of §112 ¶1 is a description of the invention. Accordingly, the instant Application does provide an adequate written description for one of ordinary skill in the art to practice the instant invention.

Regarding the enablement requirement of §112, the Federal Circuit has held that "[t]he specification need not explicitly teach those in the art to make and use the invention; the

requirement is satisfied if, given what they a ready know, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation'." (*Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1334 (Fed. Cir. (2003)). The Claims as currently amended are fully enabled by the Specification of the instant application in combination with the general knowledge of one of ordinary skill in the art.

Further as described in *Capon*, as the skill in the art progresses so does the analysis of the inventions in said art. The Examiner alleges that the instant disclosure presents no guidance or working examples for practicing the instant invention. Applying *Capon* and the relative state of the art at the time of filing, one of ordinary skill would be able to create the working examples the Examiner asserts are lacking and the guidance needed would be minimal, if any was needed at all, as molecular biological techniques are well known to the skilled artisan. The skill in the art at the time of filing was such that creation of polynucleotides, in general, was routine.

Further still, the Examiner renders assertions regarding substituting amino acids, the predictability of results and obtaining the desired activity in the end product. Applicants assert that one of ordinary skill in the art would be able to determine to a sufficient degree, as to not require undue experimentation, amino acid substitutions. First, a skilled artisan would know that in certain positions, certain amino acid changes would render the subsequent protein inactive and would avoid using said substitutions. Along those lines, MPEP 2164.08(b) clearly states that "[t]he presence of inoperative embodiments within the scope of a claim does not necessarily render a claim non-enabled." Thus, even if the skilled artisan substituted an amino acid at a non-optimum position, said invention is still enabled. Second, computational techniques were available at the time of filing for structural predictions based on sequence listings. (*See e.g.*, The Boston University Protein Sequence Analysis server available at http://bmerc-www.bu.edu/psa/). Accordingly, one of ordinary skill in the art would have ready knowledge of and predictability of activity after amino acid substitution.

Further yet, the Examiner asserts that to practice the instant invention "would require years of inventive effort." The Examiner is directed to MPEP 2164.06 wherein *In re Wands* is quoted as stating "[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible" if the experimentation is routine or if the specification provides guidance (858 F.2f 731, 737 (Fed. Cir. 1988)) (citing *In re Angstadt* 537 F.2d 489, 502-04 (CCPA 1976)). Applicants assert 1) that plenty of guidance is provided in the instant Specification in regards to the techniques required to practice the instant invention and 2) that the

techniques are routine. As the Examiner surely knows, combinational chemistry is a known skill in the art and the skilled artisan would have been able to use said techniques to screen for active peptides. Accordingly, the instant invention is enabled.

Applicants respectfully submit that for at least the reasons listed above, the rejections under 35 USC §112, first paragraph, written description and enablement, should be withdrawn and an indication of allowance should appear in the next paper from the Office. Favorable action is solicited.

Rejections under 35 USC §103

Claims 1-4, 6 and 8-14 are rejected for allegedly being obvious in light of the art cited by the Examiner in the instant Action. Applicants have amended the instant claims thereby rendering the rejection moot.

The instant invention is drawn related creating fusion proteins between for example fatty acid biosynthesis genes such as a Δ-4 desaturase and the beta-barrel part of the LOX gene. Such fusion proteins are directed to the liposomes or lipid bodies. At said lipid related areas, the fusion protein are integrated into the membranes,

Hohne et al. describes the biochemical characterization of a lipid body lipoxygenase from cucumber. Such descriptions are disclosed, for example, on the first page, left column, second paragraph with the following, "[w]e first analyzed the properties of fragments from the lipid body lipoxygenase." The skilled artisan is described, on the second page, left column, that "[l]ipoxygenase is present in plant cells as many isoforms expressed differently during plant development and located in different tissues and compartments." One of ordinary skill in the art is further taught in the discussion section that "the part of the molecule that may represent a targeting sequence and the domain of this lipoxygenase form that may be responsible for its attachment to the lipid body surface remain to be determined from the primary structure." Hohne et al. fails to teach or suggest the targeting of fusion proteins between the targeting sequence and a sequence from the fatty acid biosynthesis chain to liposomes. Thus, Hohne fails to teach or suggest anything in the technical field of fusion proteins; the reference is related to the physiological characterization of a lipoxygenase from cucumber. Accordingly, there is no teaching or suggestion for the skilled artisan that said targeting sequence can be used in fusion proteins for directing the fusion protein to liposomes. Consequently, one of ordinary skill in the art would not be motivated to combine or modify Hohne, a reference that is in an entirely

different technical field and that fails to teach or suggest the fusion proteins of the instant invention, with the teachings of others with the expectation of successfully arriving at and practicing the invention of the various claims.

Ohlrogge et al. discloses a polynucleotide encoding a Δ-4 desaturase and its function in the fatty acid biosynthesis chain to synthesis petroselinic acid. Ohlrogge fails to teach or suggest about targeting sequences as such or in combination with other sequences. Further, the Ohlrogge is wholly silent regarding fusion proteins. As with Hohne et al., one of ordinary skill in the art would not be motivated to combine or modify the teachings of Ohlrogge with those of others and arrive at the invention of the various claims.

Yamamoto et al. is drawn to a method of producing peptides or proteins which makes it possible to cause a wide range of host microorganisms to produce heterologous fusion proteins and then excise desired gene products efficiently from the fusion proteins using a highly specific enzyme. Yamamoto is in the technical field of protein production and protein purification, which is an entirely unrelated technical field. Further, Yamamoto et al. fails to teach or suggest the fusion process for combining LBLOX and desaturase to target lipid bodies. Accordingly, one of ordinary skill in the art would not be motivated to combine or modify Yamamoto with those of others to arrive at the invention of the various claims.

In view of the above, then, absent the Applicant's disclosure, there is simply no teaching, suggestion or motivation in the art to combine/modify the teaching of the various references in the manner of the Applicant to arrive at the claimed invention. Similarly, common sense or the general level of skill in the art does not lead the skilled artisan to create the invention of the instant claims. Accordingly, Applicants respectfully submit that the instant claims are nonobvious in view of the cited art.

Conclusion

Applicants respectfully submit that the present application is in condition for allowance, which action is courteously requested. Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 14-1437. Please credit any excess fees to such deposit account.

Respectfully submitted,
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